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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,379	05/30/2001	Donald L. Durden	1857-P02575US1	7235

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EXAMINER	
YU, MISOOK	
ART UNIT	PAPER NUMBER
1642	6

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,379	DURDEN, DONALD L.	
	Examin r	Art Unit	
	Misook Yu	1642	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-88* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4 drawn to method to identify agents that modulates PTEN activity by assaying AKT, classified in 435, subclass 6.

II. Claim 5, drawn to agent(s) that is identified by group I invention, unclassifiable because of unknown nature of the agent(s).

III. Claims 6-12, drawn to method of gene therapy for treatment of cancer using PTEN gene, classified in class 514, subclass 44.

IV. Claims 13-17 drawn to method to identify agents that modulates PTEN activity by assaying microvesssel density formation, classified in class 435 subclass 4.

V. Claim 18, drawn to agent(s) that is identified by group IV invention, unclassifiable because of unknown nature of the agent(s).

VI. Claim 19-22, drawn to method to identify agents that modulates PTEN activity by assaying TSP-1, classified in 435, subclass 6.

VII. Claim 23, drawn to agent(s) that is identified by group VI invention, unclassifiable because of unknown nature of the agent(s).

VIII. Claim 24-27, drawn to method to identify agents that modulates PTEN activity by assaying VEGF-1, classified in 435, subclass 6.

IX. Claims 28, drawn to agent(s) that is identified by group VIII invention, unclassifiable because of unknown nature of the agent(s).

X. Claims 29-32, drawn to method to identify agents that modulates PTEN activity by assaying TIMP3, classified in 435, subclass 6.

XI. Claims 33, drawn to agent(s) that is identified by group X invention, unclassifiable because of unknown nature of the agent(s).

XII. Claims 34-37 drawn to method to identify agents that modulates PTEN activity by assaying MMP-9, classified in 435, subclass 6.

XIII. Claims 38, drawn to agent(s) that is identified by group X invention, unclassifiable because of unknown nature of the agent(s).

XIV. Claims 39-42, drawn to method for method to identify agents that modulates PTEN activity by assaying invasiveness of cells, classified in 436, subclass 62.

XV. Claims 43, drawn to agent(s) that is identified by group X invention, unclassifiable because of unknown nature of the agent(s).

XVI. Claims 44-48, drawn to method to identify agents that modulates PTEN activity by assaying PTEN phosphatase activity, classified in 435, subclass 21.

XVII. Claims 49-55, drawn to method to identify agents that modulates PTEN activity by chemical combinatorial library, classified in 435, subclass 4.

XVIII. Claims 56-60, drawn to method of preventing or inhibiting inflammatory disease using PTEN agonist, unclassifiable due to unknown nature of the agonist.

XIX. Claims 61-68, drawn to method of cancer treatment using unidentified PTEN agonist or using the agonist in combination with chemotherapeutic agent, unclassifiable due to unknown nature of the agonist.

XX. Claim 69, and 86-88, drawn to in vivo method of inhibiting p53-mediated apoptosis using PTEN inhibitor, unclassifiable due to unknown nature of PTEN inhibitor.

XXI. Claim 70, drawn to in vivo method of enhancing chemosensitivity of tumor cells to a patient having chemo-resistant tumor using PTEN inhibitor, unclassifiable due to unknown nature of PTEN inhibitor.

XXII. Claim 71, drawn to in vivo method of enhancing radiosensitivity of tumor cells to a patient having radio-resistant tumor using PTEN inhibitor, unclassifiable due to unknown nature of PTEN inhibitor.

XXIII. Claims 72-74, drawn to method of gene therapy using native PTEN for the treatment of inflammatory condition in a patient having a mutation in PTEN, classified in class 514, subclass 44.

XXIV. Claims 75-77, drawn to in vivo method of inhibiting immunoreceptor signaling using PTEN agonist, unclassifiable due to unknown nature of the small molecule.

XXV. Claims 78 and 79, drawn to in vivo method of augmenting an immune reaction using PTEN inhibitor, unclassifiable due to unknown nature of PTEN inhibitor.

XXVI. Claims 80-83, drawn to in vivo method of inhibiting aberrant angiogenesis using PI3 inhibitor, unclassifiable due to unknown nature of the inhibitor.

XXVII. Claim 83-85, drawn to in vivo method of inhibiting aberrant angiogenesis using either AKT inhibitor or AKT inhibitor in combination with PI3 inhibitor, unclassifiable due to unknown nature of the inhibitors.

The inventions are distinct, each from the other because of the following reasons:

Inventions groups I, IV, VI, VIII, X, XII, XIV, XVI, and XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions groups 4-8 use different assay systems requiring materially different reagents and method steps.

Inventions groups II, V, VII, IX, XI, XIII, XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions groups are agent(s) that is identified by materially different methods steps and may or may not be an identical agent. If an agent identified by the materially different method steps of invention groups I, IV, VI, VIII, X, XII, XIV, XVI, and XVII are identical, then restriction between the invention groups II, V, VII, IX, XI, XIII, and XV will be withdrawn later. In order for this to happen, the applicant is requested to specify the exact chemical nature of the identified agent.

Inventions groups III, XVIII-XXVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions use different in vivo treatment method requiring either materially different methods or for different objectives with different degrees of expectation for success of each of the in vivo treatment.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification. The search required for each of the above inventions is not coextensive with regard to the literature and the sequence searches. Further, a reference which would anticipate the invention of any one group would not necessarily anticipate or make obvious the any of the other groups. For these reasons, restriction for examination purposes is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, group I and II above are generic.

Group 1 contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 3). The different DNA molecules are patentably distinct because they are different in chemical structure and molecular formulas. If group I is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Group III contains claims generic to a plurality of disclosed patentably distinct species (listed in claims 8). Claims 9-12 will be examined as they are drawn to an elected species in claim 8. The different vectors are patentably distinct because they are different in chemical structure and molecular formulas. If group II is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Group IV contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 15). The different DNA molecules are patentably distinct because they are different in chemical structure and molecular formulas. If group I is

elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Group VI contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 21). The different DNA molecules are patentably distinct because they are different in chemical structure and molecular formulas. If group VI is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Group VIII contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 26). The different DNA molecules are patentably distinct because they are different in chemical structure and molecular formulas. If group VIII is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Group X contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 31). The different DNA molecules are patentably distinct because they are different in chemical structure and molecular formulas. If group X is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Group XII contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 36). The different DNA molecules are patentably distinct because they are different in chemical structure and molecular formulas. If group XII is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Group XIV contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 41). The different DNA molecules are patentably distinct because they are different in chemical structure and molecular formulas. If group XIV is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Group XVIII contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 57). The different human diseases are patentably distinct because they are different etiology and respond differently to a given treatment. If

group XVIII is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Group XIX contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 65). The different chemotherpeutic agents are patentably distinct because they are different product with different chemical structures and molecular formulas. If group XIX is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Group XX contains claims generic to a plurality of disclosed patentably distint species of two classes of genuses. First, the different the conditions disclosed in claim 86 are patentably distinct because they have different etiology and respond differently to a given treatment. Second, the different cell types disclosed in claim 88 are distinct because they are different cells that require different method for an PTEN inhibitor to be targeted, for example to order to reach brain cells with the inhibitor, brain barriers should be overcome, which requires special considerations. If group XX is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the two genuses, even though this requirement is traversed.

Group XXIII contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 74). The different cell types are patentably distinct because they are different cells that have different degrees of success in gene therapy and require different methods to target a desired gene. If group XXIII is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Group XXIV contains claims generic to a plurality of disclosed patentably distict species of two classes of genuses. First, the different immunoreceptor disclosed in claim 76 are patentably distinct because they are different in molecular and structural formulas. Second, the conditions disclosed in claim 77 are patentably distinct because they have different etiology and respond differently to a given treatment. If group XXIV is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the two genuses, even though this requirement is traversed.

Group XXVI contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 81). The different human diseases are patentably distinct because they are different etiology and respond differently to a given treatment. If group XXVI is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Group XXVII contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 84). The different human diseases are patentably distinct because they are different etiology and respond differently to a given treatment. If group XXVII is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu, Ph.D.
August 8, 2002

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600